

Kansas Medicaid Supplemental Drug Rebate Agreement

This Agreement is entered into by and between the Kansas Health Policy Authority, hereinafter referred to as KHPA, located at 900 SW Jackson Street, Room 900N, Topeka, Kansas 66612-1220 and **CONTRACTOR'S LEGAL NAME**, hereinafter referred to as CONTRACTOR located at **CONTRACTOR'S ADDRESS**.

WHEREAS, Kansas Medicaid provides reimbursement for, or coverage of, prescription drug products to Medicaid recipients;

WHEREAS, a preferred drug list has been established for Kansas Medicaid;

WHEREAS, the Centers for Medicare and Medicaid Services (CMS) and CONTRACTOR have entered into a drug rebate agreement pursuant to Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8);

WHEREAS, KHPA and CONTRACTOR have agreed to enter into a supplemental drug rebate agreement;

NOW, THEREFORE, for and in consideration of their mutual promises, the parties hereby agree as follows:

1. DEFINITIONS

- 1.1 AMP shall mean the Average Manufacturer Price as set forth in 42 U.S.C. ' 1396r-8, as such statute may be amended from time to time.
- 1.2 Best Price shall mean Best Price as set forth in 42 U.S.C. Sec. 1396r-8, as such statute may be amended from time to time, excluding State Supplemental Rebate amounts.
- 1.3 CMS Agreement means CONTRACTOR's drug rebate contract with the Centers for Medicare & Medicaid Services (CMS), entered pursuant to Section 1927 of the Social Security Act (42 U.S.C. Sec. 1396r-8).
- 1.4 CMS Basic Rebate means, with respect to the covered product(s), the quarterly payment by manufacturer pursuant to manufacturer's CMS Agreement, made in accordance with Section 1927(c)(1) or Section 1927(c)(3) of the Social Security Act (42 U.S.C. Sec. 1396r-8(c)(1)) and 42 U.S.C. Sec. 1396r-8(c)(3)).
- 1.5 CMS CPI Rebate means, with respect to the covered product(s), the quarterly payment by manufacturer pursuant to manufacturer's CMS Agreement, made in accordance with Section 1927(c)(2) of the Social Security Act (42 U.S.C. Sec. 1396r-8(c)(2)).

- 1.6 “Contract Quarter” means the quarters ending on March 31, June 30, September 30, and December 31 of each calendar year during the term of this Agreement.
- 1.7 “Kansas Medicaid” means the joint federal and state medical assistance program as established and defined pursuant to Title 42 U.S.C. 1396, et seq., that provides reimbursement for or coverage of prescription drug products to Medicaid recipients.
- 1.8 Kansas Medicaid Preferred Drug List means the preferred drug list established for Kansas Medicaid.
- 1.9 Kansas Medicaid Recipient shall mean any person enrolled in Kansas Medicaid and eligible to receive prescription drug benefits.
- 1.10 “CONTRACTOR Product(s)” means only the following pharmaceutical product(s): ???
- 1.11 “State Utilization Data” means the data used by KHPA to reimburse pharmacy providers under the Kansas Medicaid Program. State Utilization Data excludes data from covered entities identified in Title 42 U.S.C. Sec. 256b(a)(4) in accordance with Title 42 U.S.C. Sec. 256b(a)(4)(A) and 1396r-8(a)(5)(C). State Utilization shall not include any products dispensed to Medicaid recipients by pharmacies outside of the United States.
- 1.12 “State Supplemental Rebate” means, with respect to the covered product(s), the quarterly payment by manufacturer pursuant to Section 2.1 and 2.2 of this Agreement.

2. DISCOUNT WITH RESPECT TO UTILIZATION OF PRODUCTS

- 2.1 Manufacturer will calculate and provide KHPA a CMS Rebate for the covered product(s), which includes the CMS Basic Rebate and CMS CPI Rebate, as appropriate. The CMS Rebate represents the discount obtained by multiplying the units of the covered product(s) dispensed to Kansas Medicaid recipients by pharmacies in the United States in the preceding quarter by the per unit rebate amount provided to KHPA by CMS. CMS will calculate the CMS Rebate amount in accordance with manufacturer's CMS Agreement. Manufacturer's obligation for CMS Rebates will continue for the duration of the Manufacturer's CMS Agreement.
- 2.2 In addition to the CMS Rebates described in Section 2.1 of this Agreement, manufacturer will remit to the State a State Supplemental

Rebate for the covered product(s) such that the total rebate amount received by KHPA shall be shown in Schedule A. CONTRACTOR's obligation for State Supplemental Rebates will begin on the effective date, provided, however, that CONTRACTOR shall not pay any supplemental rebates until KHPA provides CONTRACTOR with written confirmation of: (a) CMS's approval of the Kansas State Supplemental Rebate Program, included herewith as Attachment B, and (b) CMS's finding that the State Supplemental Rebate does not establish a new 'Best Price' for purposes of CONTRACTOR's CMS Agreement. (See Sec. 3.4)

- 2.3 Utilization of CONTRACTOR products by Kansas Medicaid Recipients is subject to the State Supplemental Rebates set forth in Schedule A, provided that KHPA places all such CONTRACTOR products on the Kansas Medicaid Preferred Drug List as of the effective date, with the status set forth in Schedule A.
- 2.4 No State Supplemental Rebates shall be paid to KHPA when KHPA is in default of any of its obligations under this Agreement.
- 2.5 Payment of State Supplemental Rebates is contingent upon the conditions set forth in Section 8.9.

3. KHPA' OBLIGATIONS

- 3.1 In consideration of the State Supplemental Rebates provided under this Agreement, KHPA, directly and through its respective affiliates and agents, agrees that it will:
 - (i) place and maintain all CONTRACTOR products on the Kansas Medicaid Preferred Drug List with the status set forth in Schedule A;
 - (ii) not prefer, either directly or indirectly, any competing product over a CONTRACTOR product, except for reasons of medical appropriateness or consistent with Schedule A, as applicable;
 - (iii) within five (5) days of the effective date of this Agreement and at subsequent intervals of three (3) months, list all CONTRACTOR products on all Kansas Medicaid Preferred Drug Lists (including but not limited to printed and electronic versions of drug lists) with the status specified in Schedule A, as applicable;
 - (iv) independently undertake actions that appropriately reflect the preferred status of and any plan benefit design attributes listed in Schedules A relevant to CONTRACTOR products, including communication on a regular basis of the preferred status of

products to Kansas Medicaid physicians, pharmacists and other appropriate parties (with a copy provided to CONTRACTOR);

- (v) within 30 days of the effective date of this Agreement, and immediately upon making any changes to that portion of the Kansas Medicaid Preferred Drug List related to a therapeutic category in which a CONTRACTOR product competes, provide CONTRACTOR with a copy of the Kansas Medicaid Preferred Drug List and internet web site addresses (if any) where such formulary listings may be found;
 - (vi) review for Kansas Medicaid Preferred Drug List acceptance new products (including any products marketed by a joint venture) within 6 months of written notification by CONTRACTOR that the new product has been approved by the FDA and released for marketing;
 - (vii) review for acceptance new products (including any products marketed by a joint venture) in a new therapeutic class within 6 months of written notification by CONTRACTOR that the new product has been approved by the FDA and released for marketing;
 - (viii) review for Kansas Medicaid Preferred Drug List acceptance new indications or recommendations for CONTRACTOR products (including any products marketed by a joint venture) within 6 months of notification by CONTRACTOR that the FDA has approved a new indication or recommendation for a CONTRACTOR product.
- 3.2 KHPA shall develop the content of all communications regarding products independent of the influence, control or participation of CONTRACTOR.
- 3.3 KHPA shall submit State Utilization Data to CONTRACTOR on a quarterly basis. The data will be based on paid claims data (data used to reimburse pharmacy providers) for the Kansas Medicaid Program. KHPA shall seek State Supplemental Rebates only with respect to utilization of CONTRACTOR products that are eligible for a CMS Basic Rebate and CMS CPI Rebate.
- 3.4 KHPA warrants that it has received CMS approval to receive State Supplemental Rebates as provided under this agreement and that CONTRACTOR's payment of State Supplemental Rebates under this Agreement will not affect the Best Price or AMP used by CONTRACTOR to determine rebates paid pursuant to 42 U.S.C. Sec. 1396r-8.

4. SUBMISSION OF DATA AND PAYMENT OF REBATES

- 4.1 Within 90 days following the close of each contract quarter, KHPA shall deliver to CONTRACTOR, in a mutually acceptable electronic format, State Utilization Data. KHPA shall deliver the State Utilization Data to CONTRACTOR in the same manner, and at the same time that State Utilization Data is submitted under Kansas Medicaid. CONTRACTOR is not required to pay State Supplemental Rebates with respect to utilization that occurred during a contract quarter for which complete and accurate State Utilization Data is received by CONTRACTOR more than 180 days following the close of that contract quarter.
- 4.2 Within 90 days after receipt by CONTRACTOR of complete and accurate State Utilization Data as set forth above and provided the conditions of Section 8.9 have been met, CONTRACTOR shall make payment of State Supplemental Rebates due under Section 2 hereof.
- 4.3 If any error is discovered in the data submitted or State Supplemental Rebates paid under this Agreement, including the submission of data with respect to patients or utilization not subject to State Supplemental Rebates under this Agreement, the State Supplemental Rebates due hereunder shall be appropriately adjusted to reflect the error and CONTRACTOR or KHPA shall make payment to the other as required to reflect such adjustment. If CONTRACTOR has overpaid KHPA, CONTRACTOR may, at its sole discretion, deduct the amount of the overpayment from future discount payments due pursuant to this Agreement.
- 4.4 KHPA will immediately return to CONTRACTOR all State Supplemental Rebates paid under this Agreement if CMS's approval of the Kansas State Supplemental Rebate Program is found to be invalid.

5. NOTICES

All notices under this Agreement shall be in writing, and shall be delivered by first class mail, fax (followed by hard copy), or overnight courier. The individuals designated to receive such notices and their respective addresses are as follows:

Executive Director
Kansas Health Policy Authority
900 S.W. Jackson, Room 900N
Topeka, KS 66612-1220

Contractor's Contact Person
Contractor's Name
Contractor's Address
Contractor's City, ST, Zip Code

6. TERM & TERMINATION

- 6.1 KHPA warrants to CONTRACTOR that KHPA has full power and authority to execute this Agreement for itself, and that the execution, delivery and performance of this Agreement constitutes the valid and binding obligation of KHPA and the State of Kansas.
- 6.2 The Term of this Agreement shall be [REDACTED], through [REDACTED], unless terminated earlier as permitted hereunder. Optional one-year renewals may be available with mutual agreement of all parties and shall be accomplished through amendment.
- 6.3 This Agreement may be terminated at the option of either party upon sixty (60) days written notice to the other party, provided however that KHPA may not terminate the Agreement pursuant to this Section 6.3: (1) solely for the purpose of negotiating Supplemental Rebates that are greater than those provided for under the Agreement; or (2) because manufacturer denies a request from KHPA for Supplemental Rebates that are greater than those provided for under the Agreement.
- 6.4 This agreement may be immediately terminated upon the occurrence of any one of the following events: (a) a determination by any court or any authorized governmental authority that the arrangements and transactions under this Agreement or any similar agreement constitute a violation of any law or regulation including without limitation 42 U.S.C. Sec. 1320a-7b(b) prohibiting illegal remuneration. For the purposes of this Section 6.3, "authorized governmental authority" shall mean any officer or agency of the Federal Government (e.g., Office of the Inspector General, Department of Justice, Department of Health and Human Services) or the State of Kansas (e.g., Kansas Attorney General) having substantive jurisdiction over the subject matter of this Agreement; any state or federal program with which this Agreement is connected; any actions which must be taken by either party hereto in order to perform its obligations under this Agreement; or any laws or regulations affecting the legality of this Agreement; (b) a determination by CMS or any other legal entity that the State Supplemental Rebates paid or payable by CONTRACTOR under this Agreement will affect or be included in Best Price calculations for determining rebates paid pursuant to 42 U.S.C. Sec. 1396r-8 or (c) KHPA's failure to provide written confirmation of CMS's approval of the Kansas State Supplemental rebate Program, of which this Agreement forms a part, within a reasonable period of time.

7. CONFIDENTIALITY

7.1 CONTRACTOR certifies that the rebate formula and pricing information set forth in this Agreement as well as any other information concerning rebate amounts, supplemental rebate amounts, and price data are trade secrets. KHPA agrees that this certification is reasonable. Accordingly, if KHPA receives a request for the rebate amounts, supplemental rebate amounts or price data, KHPA will assert an exception other than from CMS or a federal agency of appropriate oversight to disclosure under Section 1927(b)(3)(D) of the Social Security Act for information that is confidential under that law, and will assert an exception to disclosure under K.S.A. 60-432: “The owner of a trade secret has a privilege, which may be claimed by the owner or his or her agent or employee, to refuse to disclose the secret and to prevent other persons from disclosing it if the judge finds that the allowance of the privilege will not tend to conceal fraud or otherwise work injustice.” KHPA will refrain from producing the document or information and will object to disclosure under K.S.A. 45-221 of the Kansas Open Records Act, which concerns “records not required to be open:” “(a) Except to the extent disclosure is otherwise required by law, a public agency shall not be required to disclose: . . . (2) Records which are privileged under the rules of evidence, unless the holder of the privilege consents to the disclosure.” In addition, regardless of whether KHPA receives a request, KHPA agrees to preserve the confidentiality of the rebate amounts, supplemental rebate amounts, and price data provided pursuant to this Agreement and will not duplicate, disclose or use such information, except in furtherance of the purposes of this Agreement or as may be required by judicial order.

In the event that either party is required by law to disclose any provision of this Agreement or any information provided pursuant to this Agreement to any person, such party shall provide advance written notice to the other party sufficiently in advance of the proposed disclosure to allow the other party to seek a protective order or other relief.

To the extent that KHPA utilizes the services of a third-party to develop and maintain the Preferred Drug List (PDL) or to administer any portion of this Agreement, all provisions of Section 7.1 shall apply to the third-party, and KHPA shall have the third-party sign a written agreement ensuring the third-party’s compliance with all aspects of Section 7.1 before disclosing any information to the third-party. Section 7.1 shall survive termination or expiration of this Agreement.

7.2 The parties agree not to disclose, to each other or to a third party, any information protected as confidential under state or federal law, including but not limited to information revealing the identity of Medicaid recipients. The foregoing sentence shall not prevent the disclosure by manufacturer to KHPA of information regarding the National Rebates for covered products.

7.3 KHPA represents and warrants that it will not provide any patient identifiable information to CONTRACTOR. KHPA further represents and warrants that it will not provide any other information the disclosure of which is prohibited by laws or regulations governing confidentiality of any subject matter, including but not limited to medical records.

8. AUDIT, MISCELLANEOUS

8.1 CONTRACTOR shall have the right, upon written notice, to review and audit data and other contract related documentation of KHPA as necessary to verify KHPA's performance and compliance with their obligations under this Agreement. An independent third-party auditor may, at CONTRACTOR's sole discretion, conduct such review and audit, provided that such auditor shall agree to maintain the confidentiality of KHPA's confidential data and documentation. The terms of this Section 8.1 shall survive termination of this Agreement for a period of seven (7) years.

8.2 Schedule A is part of this Agreement.

8.3 If CONTRACTOR discontinues the manufacture, sale or distribution of any CONTRACTOR product or decides to transfer or license any CONTRACTOR product to a third party, then CONTRACTOR shall notify KHPA, such product shall be removed from the definition of "CONTRACTOR products", and no discount shall be payable with respect to utilization of such product that occurred after such discontinuance.

8.4 At the time of each Supplemental Rebate payment, CONTRACTOR shall provide KHPA with reconciliation statements. KHPA is aware of this process with respect to the reporting CMS Basic Rebates and CMS CPI Rebates under the terms of the CMS Agreement and agrees to use the reconciliation statements to accurately report to CMS the CMS Basic Rebates, CMS CPI Rebates, and State Supplemental Rebates for each CONTRACTOR product for which a discount has been paid under this Agreement, to the extent required under applicable federal or state law.

8.5 KHPA represents and warrants that it has obtained any and all necessary consent(s) from any and all third parties, as required by law, regulation, ethical or professional code, contract, agreement or otherwise, to provide to CONTRACTOR all data required pursuant to Section 4.1 hereof.

8.6 CONTRACTOR and the agents and employees of CONTRACTOR in the performance of this Agreement, will act in an independent capacity and not as officers, employees or agents of the State of Kansas.

- 8.7 Nothing in this Agreement will be construed so as to require the commission of any act contrary to law. If any provision of this Agreement is found to be invalid or illegal by a court of law, or inconsistent with federal requirements, this Agreement will be construed in all respects as if any invalid, unenforceable, or inconsistent provision were eliminated, and without any effect on any other provision. The parties agree to negotiate replacement provisions, to afford the parties as much of the benefit of their original bargain as is possible.
- 8.8 Inasmuch as the State Supplemental Rebate required by this Agreement is for Kansas Medicaid recipients, KHPA warrants that the State Supplemental Rebate does not establish a new 'Best Price' or AMP for purposes of CONTRACTOR's CMS Agreement.
- 8.9 Performance under this Agreement shall be contingent on the non-occurrence of the events described in Section 6.4(b) of this Agreement, and on CMS's valid approval of the Kansas Supplemental Rebate Program of which this Agreement forms a part.
- 8.10 KHPA warrants that the business arrangement contemplated by this Agreement is not subject to the provisions of 42 U.S.C. Sec. 1320a-7b(b) prohibiting illegal remuneration. Should the above provisions apply, KHPA warrants that the business arrangement contemplated by this Agreement meets the discount exception found in 42 U.S.C. Sec. 1320a-7b(b)(3)(A), which excludes from prohibited activities the practice of discounting or other reductions in price obtained by a provider of services or other entity under a Federal health care program, if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program. KHPA currently provides CMS full and unfettered access to all information held by KHPA regarding the implementation of the Kansas Medicaid Program, and shall continue to do so throughout the term of this Agreement.
- 8.11 This Agreement shall be governed by and construed in accordance with the laws of the State of Kansas.
- 8.12 Failure of either party hereto to complain of any act or omission on the part of the other party hereto shall not be deemed a waiver of any breach or default of any term or condition of this Agreement. No waiver by either party of any breach or default of any term or condition of this Agreement shall be deemed a waiver of any other or subsequent breach or default.

- 8.13 The parties will resolve any disputes relating to the Agreement in accordance with generally applicable procedures followed by KHPA or CMS in disputes concerning rebates paid pursuant to 42 U.S.C. Sec. 1396r-8.
- 8.14 Noncompliance with any obligations hereunder due to force majeure, such as acts of God, laws or regulations of any government, war, terrorism, civil commotion, destruction of production facilities and materials, fire, earthquake, or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers, and any other causes beyond the reasonable control of the parties, shall not constitute breach of contract.
- 8.15 This Agreement constitutes the entire agreement of the parties and supersedes all prior agreements, written or oral, between the parties (except confidentiality agreements, which shall survive execution hereof).
- 8.16 Modification or amendment to this agreement shall be in writing, and executed with the same formality as the original.
- 8.17 This Agreement shall bind the parties hereto and their successors and assigns, provided that neither party shall have the right to assign this Agreement or any part thereof to a third party without the prior written consent of the other party.
- 8.18 The Provisions found in Contractual Provisions Attachment (Form DA-146a, Rev. 1-01), Schedule A, "Preferred Drug List Status Requirements and Discount Calculation" and Attachment B, CMS approval letter, which are attached hereto, are hereby incorporated in this contract and made a part thereof.

**KANSAS HEALTH POLICY
AUTHORITY**

By: _____
Printed Name
Printed Title

By: _____
Marcia Nielsen, PhD, MPH
Interim Executive Director

Date: _____

Date: _____